Pharmacy

Prior Authorization Criteria for Testosterone Replacement Therapies

Background

The testosterone replacement therapy (TRT) agents are used for conditions associated with a deficiency or absence of endogenous testosterone. Agents in this class include testosterone transdermal 2% gel pump (Fortesta), testosterone transdermal patch (Androderm), testosterone transdermal gel tubes (Testim), testosterone buccal tablets (Striant), testosterone transdermal 1% gel pump and gel packets (Androgel 1%), testosterone transdermal 1.62% gel pump (Androgel 1.62%), and testosterone transdermal solution (Axiron).

Step Therapy applies to this class. Step therapy involves prescribing a safe, cost effective medication as the first step in treating a medical condition. The preferred medication is a medication that offers the best overall value in terms of safety, effectiveness, and cost. Non-preferred drugs are only prescribed if the first step medications are ineffective or poorly tolerated. A trial of **Fortesta** is required prior to using other transdermal and buccal TRTs.

Prior Authorization Criteria for Testosterone Replacement Therapies

Manual PA criteria for **ALL** transdermal and buccal testosterone replacement products:

1. Patient is male and has a diagnosis of hypogonadism evidenced by 2 or more morning testosterone levels in the presence of symptoms usually associated with hypogonadism;

*Note that coverage for use in women or use in adolescents under the age of 17 is not approved and will be by appeal only.

In addition to the above criteria, the following PA criteria would apply specifically to transdermal gel tubes (**Testim**), transdermal patch (**Androderm**), buccal tablets (**Striant**), transdermal 1% gel pump and gel packets (**Androgel 1%**), transdermal 1.62% gel pump (**Androgel 1.62%**), and transdermal solution (**Axiron**):

- The patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members (for **Striant** and **Androderm** only).
- The patient has tried transdermal 2% gel pump (**Fortesta**) for a minimum of 90 days **AND** failed to achieve total testosterone levels above 400ng/dL (lab must be drawn 2 hours after **Fortesta** application) AND denied improvement in symptoms.
- The patient has a contraindication or relative contraindication to **Fortesta** (e.g., hypersensitivity to a component [including alcohol]; concomitant disulfiram use) that does not apply to **Testim,**

Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron.

- The patient has experienced a clinically significant skin reaction to **Fortesta** that is not expected to occur with **Testim, Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron**.

Criteria approved through the DOD P&T Committee process August 2012

Prior Authorization Request Form for Androderm, AndroGel, Axiron, Striant, Testim

5693

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

MAIL ORDER and RETAIL	• The provider may **call**: **1-866-684-4488** or the completed form may be **faxed** to: **1-866-684-4477** • The patient may attach the completed form to the prescription and **mail** it to: **Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954** or **email** the form only to: **TPharmPA@express-scripts.com**

Prior authorization criteria and a copy of this form are available at: http://pec.ha.osd.mil/forms_criteria.php. This prior authorization has no expiration date.

Medication requested:

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

Step 2 **Please complete the clinical assessment:**

1. Is the patient a male who is 17 years of age or older?	☐ Yes Go to question 2	☐ No **Coverage not approved**
2. Does the patient have a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dl ?	☐ Yes Go to question 3	☐ No **Coverage not approved**
3. Is the patient experiencing symptoms usually associated with hypogonadism?	☐ Yes Go to question 4	☐ No **Coverage not approved**
4. Has the patient tried Fortesta for a minimum of 90 days AND failed to achieve total testosterone levels above 400 ng/dl (labs drawn 2 hours after Fortesta application) AND without improvement in symptoms?	☐ Yes **Sign and date below**	☐ No Go to question 5
5. Does the patient have a contraindication or relative contraindication to Fortesta that does not apply to the requested agent?	☐ Yes **Sign and date below**	☐ No Go to question 6
6. Has the patient experienced a clinically significant skin reaction to Fortesta that is not expected to occur with the requested agent?	☐ Yes **Sign and date below**	☐ No Go to question 7
7. Is the request for Striant or Androderm?	☐ Yes Go to question 8	☐ No **Coverage not approved**
8. Does the patient require a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members?	☐ Yes **Sign and date below**	☐ No **Coverage not approved**

Step 3 **I certify the above is true to the best of my knowledge.**
Please sign and date:

_____ _____

Prescriber Signature Date

[6 February 2013]